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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,234	04/06/2001	Tae-Shin Park	0136/OJ067	3081

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EXAMINER	
TUNG, JOYCE	
ART UNIT	**PAPER NUMBER**
1637	
MAIL DATE	**DELIVERY MODE**
05/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/807,234	PARK ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-25,27,29 and 31-40* is/are pending in the application.

4a) Of the above claim(s) *12-35. 27,29 and 31-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The applicant's response filed 3/29/07 to the Office action has been entered. Claims 12-25, 27, 29 and 31-40 are pending. Claims 39-40 are examined.

1. Claims 39-40 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Meijer et al. (6352,825, issued March 5, 2002), in view of Stewart et al. (Journal of Virology, 1996, Vol. 70(5), Buck et al. (BioTechniques, 1999, Vol. 27(3), pg. 528-536), Day et al. (Biochem. J., 1990, Vol. 267, pg. 119-123) and Lukhtanov et al. (6,339,147, issued October 15, 2002)

Meijer et al. disclose HPV type-specific oligonucleotide probe for the detection of HPV. The probes as listed are identical to SEQ ID NOs: 1-11 and 13-19 of the instant claims (See column 9, lines 5-67), for example, SEQ ID NO: 31, specific for HPV-16; SEQ ID NO: 32, specific for HPV-18; SEQ ID NO: 34, specific for HPV-31; SEQ ID NO: 35, specific for HPV-33; SEQ ID NO: 37, specific for HPV-35; SEQ ID NO: 38, specific for HPV-39; SEQ ID NO: 43, specific for HPV-45; SEQ ID NO: 44, specific for HPV-51; SEQ ID NO 45, specific for HPV-52; SEQ ID NO: 47, specific for HPV-56; SEQ ID NO: 48, specific for HPV-58; SEQ ID NO: 51, specific for HPV-66; SEQ ID NO: 29, specific for HPV-6; SEQ ID NO: 30, specific for HPV-11; SEQ ID NO: 36, specific for HPV-34; SEQ ID NO: 39, specific for HPV-40; SEQ ID NO: 40, specific for HPV-42 and SEQ ID NO: 42, specific for HPV-44 are respectively identical to SEQ ID NO: 1-11 and 13-19 of the instant claims.

Meijer et al. do not disclose any oligonucleotide probe, which is identical to SEQ ID NO: 12 in the instant claims.

Stewart et al. disclose the study of intratype human papillomavious (HPV) sequence variation in a worldwide collection of cervical specimens (See pg. 3127, the abstract). Based

upon the nucleic acid search report, a variant of HPV-59 has been sequenced over the My09/11 consensus primer region. The sequence of HPV-59 has been submitted to Genbank in which Accession numbers U45930 to U45933 are to the HPV-59 sequences and SEQ ID NO: 12 is part of the sequence of HPV-59 (See pg. 3128, column 2, third paragraph and the attached nucleic acid search report).

None of the references above discloses choosing a nucleic acid probe from a well-known nucleic acid for a specific detection.

Buck et al. disclose how to make and use numerous successful primers from a known nucleic acid sequence (See pg. 528, the Abstract).

One of ordinary skill in the art would have been motivated to apply the HPV type-specific oligonucleotide probes of Meijer et al. which are identical to SEQ ID NO: 1-11 and 13-19 on a chip for the diagnosis of HPV because as disclosed by Meijer et al. the oligonucleotide probes are specific for the detection of HPV (See column 9, lines 5-67). Moreover one of ordinary skill in the art would have also been motivated to make probes including SEQ ID NO: 12 from the known nucleic acid sequence of HPV-59 as disclosed by Stewart et al. because Buck et al. disclosed that numerous primers generated from different regions of a target sequence all worked well in amplification reactions. Thus, such primers would have been expected to work in the combined method of Meijer et al. It would have been prima facie obvious to use SEQ ID NO: 1-19 for detecting HPV.

Meijer et al. do not disclose that the primer is biotin labeled in detecting HPV.

Day et al. disclose the method of incorporation of biotin into the polymerase chain reaction products for the detection of the amplified DNA (See pg. 1990, column 1, second

paragraph). The method applies the 5' biotinylated primer or biotin 16-dUTP to label the amplified products (See pg. 1990, column 1, second paragraph). The method also used second label, which is streptavidin-horseradish peroxidase (See pg. 1990, column 1, second paragraph)

Meijer et al. do not disclose that a DNA chip comprising probes having an HPV nucleic aid sequence attached to a glass slide.

Lukhtanov et al. disclose that the derivatized oligonucleotides are coupled to a solid support (See the Abstract). The invention is used for the capture and detection of nucleic acids using oligonucleotide attached to glass surfaces in array format (See column 7, lines 41-47). The oligonucleotide contains a nucleophilic amino group while the solid support contains aldehyde to form an Schiff base-type covalent linkage that attached the oligonucleotide to the solid support alternatively (See column 8, lines 27-37 and column 14, lines 15-19). Lukhtanov et al. also discuss the density of the oligonucleotides on the array (See column 14, lines 29-30) and derivatization of glass slides and preparation of oligonucleotide arrays on the glass slides (See column 23, lines 15-54).

One of ordinary skill in the art would have been motivated to modify the method of Meijer et al. by using biotinylated primer for detecting HPV as taught by Day et al. because the method of Day et al. dose not loss the amplification efficiency (See pg. 119, the Abstract) and by using the second label, streptavidin-horseradish peroxidase in sandwich assay (See pg. 1990, column 1, second paragraph), the assay does not need for separate labeled probe currently required in conventional sandwich assays. It would have been prima facie obvious to apply the biotinylated primer in PCR reaction for the diagnosis of HPV on the DNA chip with SEQ ID NO: 1-19.

One of ordinary skill in the art would have been motivated to modify the method of Meijer et al. by using a glass slide which has nucleic acid probes attached for the diagnosis of HPV infection as taught by Lukhtanov et al. because the array of Lukhtanov is via a Schiff base type bond formed between an NH_2 group attached either to the solid support or the oligonucleotide and an aromatic aldehyde attached to the other of the solid support and the oligonucleotide (See the Abstract) in which the Schiff base with aromatic-aldehyde bonds is stable, high percentage of oligonucleotide is contained on the solid support, specific attachment at either the 5'- or 3'- end is achieved and high coupling densities are obtained on unit surface (See column 4, lines 25-37). It would have been prima facie obvious to make the DNA chip with SEQ ID NO: 1-19 as probes attached to the glass slide for the diagnosis of HPV.

The response argues that Buck et al. disclose a method of selecting a nucleic acid probe for DNA sequencing, not for the HPV sub-type specific detection of DNA amplified from a clinical sample. However although the purpose of selecting the nucleic acid sequence is different in which one is used as a primer in the method of Buck et al. and another one is used as a probe in the instant claims, both primer and probe have a specificity to a target nucleic acid via a hybridization reaction to a complementary sequence. Regardless of primers or probes, it is involved in a hybridization reaction to begin with a primer extension reaction or a probe hybridization reaction. Buck et al. disclose the parameters to make nucleic acid primer, which has a specificity to a target nucleic acid via a hybridization reaction to a complementary sequence (See pg. 528, the Abstract).

The response further argues that in order for a nucleic acid sequence probe (primer) to indicate the sub-type specific presence of HPV-59, it must hybridize with HPV-59 labeled DNA

from the amplified clinical sample and provide a strong signal to be detected over the other eighteen HPV sub-type specific probes. Meijer et al., Stewart et al. and Buck et al. do not teach selecting 30 nucleotide segment of the HPV-59 DNA sequence corresponding to SEQ ID NO: 12 from the 455 nucleotide sequence discloses by Stewart et al. However, the method of the instant claims is for diagnosis of HPV infections and it is not specific for HPV-59 detection. The limitations discussed herein are not in the claims. Furthermore, even without SEQ ID NO: 12, HPV is detected because SEQ ID NOs: 1-11 and 13-19 are identical with the HPV type-specific oligonucleotide probes as taught by Meijer et al. (See the rejection above) which are combined on the chip.

The response also argues that a nucleic acid probe for DNA sequencing must necessarily begin at the 5' end of the DNA being sequenced. However, the instant claims do not recite that the nucleic acid probe has to be at the 5' end of the target sequences. The limitations discussed herein are not commensurate with the scope of the claims.

The response argues that in the method of Meijer, HPV oligonucleotide probes serve as detection agents when hybridized to the immobilized amplified DNA which is about 150 nucleotides in length while in the instant claims, the HPV-specific oligonucleotide probes are immobilized on a glass slide and the amplified DNA serves as a detection agent and these two methods have different hybridization kinetics. However, the instant claims do not recite the size of the amplified DNA. It would have been prima facie obvious to apply the nucleic acid sequences as set forth in the rejection above with the teachings of Buck et al., Day et al., and Lukhtanov et al. for diagnosing HPV infection.

The response discussed the hybridization kinetics from the study of Stillman and Tonkinson, and the study of Chan et al., Stillman and Tonkinson indicate that the length of the immobilized species and the substrate choice influences hybridization dynamics, there are no differences when hybridization occurred on a two or three-dimensional surface, the affinity of the solution phase labeled species for the immobilized species was identical for all arrayed lengths on both surfaces. Chan et al. indicate that overall kinetics of DNA hybridization to DNA on a solid support may be a very efficient process for physically realistic 2D diffusion coefficients, target concentrations and surface probe densities. Nevertheless, the limitations discussed in the study of Stillman and Tonkinson, and Chan et al. are not in the instant claims, for example, the length of the amplified DNA, target concentrations and surface probe densities. Thus, the references of Stillman and Tonkinson, and Chan et al. provided herein are irrelevant to the limitations of the claims. Based upon the discussion above, the rejection is maintained.

Summary

2. No claims are allowed.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

4. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung
May 17, 2007

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
5/24/07